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16 UNITED STATES DISTRICT COURT

17 NORTHERN DISTRICT OF CALIFORNIA

18 SHARON ZIEROTH,) Case Number: 3:20-cv-00172-MMC
19)
20 Plaintiff,)
21)
22 vs.) CASE MANAGEMENT STATEMENT
23)
24 ALEX M. AZAR II, in his capacity as)
25 Secretary of the United States Department of)
26 Health and Human Services,)
27)
28 Defendant.)
29 _____)

30 Pursuant to the Court's Order of January 14, 2020, FED.R.CIV.P. 26(f), and the Standing
31 Order for All Judges of the Northern District of California, the parties submit this report of the
32 conference held on March 20, 2020.

1 **1. Jurisdiction and Service**

2 This Court has jurisdiction pursuant to 42 U.S.C. § 1395ff(b). Plaintiff contends that
3 service was effected no later than January 17, 2020, by service on the U.S. Attorney for the
4 Northern District of California. In addition, the Attorney General of the United States was
5 served on January 21, 2020, and the Secretary was served on January 22, 2020. The Secretary
6 does not allege any deficiency of service.

7 **2. Facts**

8 Plaintiff's Statement:

9 Mrs. Sharon Zieroth was a 72 year-old mother of two and grandmother to two and wife
10 of nearly 50 years to husband Gary. Mrs. Zieroth was also a Type I, "brittle" diabetic with
11 hypoglycemic unawareness. Because of the wild and rapid swings in her glucose levels and the
12 lack of physical sensations of them, checking her glucose levels with finger-stick testing was
13 insufficient to control her diabetes, especially at night. As a result, Mrs. Zieroth was prescribed a
14 continuous glucose monitor (CGM) that automatically checks her glucose levels every five
15 minutes and can either alert her to problems or automatically adjust insulin delivery.

16 Mrs. Zieroth submitted a claim for Medicare coverage that was denied at the initial levels
17 before being approved by a Medicare ALJ. Subsequently, the Medicare Appeals Council
18 reversed the ALJ's decision on the grounds that a CGM is not "durable medical equipment"
19 (specifically, that a CGM is not "primarily and customarily used to serve a medical purpose" as
20 defined in CMS 1682-R). Mrs. Zieroth timely appealed to this Court.

22 **3. Legal Issues**

23 Plaintiff's Statement:

24 The basic legal issue is whether a continuous glucose monitor (CGM) for use by diabetics
25 is "durable medical equipment" and is, therefore, a Medicare covered benefit. More specifically,
26 the Secretary contends that a CGM is not "durable medical equipment" because the Secretary
27 alleges that it is not "primarily and customarily used to serve a medical purpose."

That issue has been litigated multiple times and the Secretary has lost each one. See *Whitcomb v. Azar*, Case No. 17-cv-14 (E.D. Wisc. Oct. 26, 2017) (Jones, J.), *Bloom v. Azar*, 2018 WL 583111 (D. Vt. January 29, 2018) (Crawford, J.) and *Lewis v. Burwell*, 2018 WL 1639687 (D. Mass. April 5, 2018) (Gorton, J.). In addition to finding that the Secretary’s position lacked merit, in each of these litigations the Court further found that the Secretary’s position lacked “substantial justification” and awarded attorney fees to plaintiff’s counsel.

Nevertheless, the Secretary has rejected Mrs. Zieroth's claim on the exact same grounds. Another issue related to the Secretary's claim that a CGM is not "durable medical equipment" is the Secretary's promulgation, without notice and comment, of CMS 1682-R seeking to exclude certain CGMs from coverage in defiance of the Medicare notice and comment statutes.

In addition to completed litigation, two other suits on the issue of whether a CGM is “durable medical equipment” are ongoing. See *Olsen v. Azar*, Case No. 19-cv-3814 (RBW) (D.D.C.) and *Lewis v. Azar*, Case No. 18-cv-2929 (RBW) (D.D.C.). The *Lewis* case is a class action seeking to certify a class of some 90,000 people whose claims were denied on the same grounds.

Defendant's Statement:

The central issue in this case is whether the continuous glucose monitor used by Mrs. Zieroth was durable medical equipment within the meaning of the Medicare statute and regulations. *See* 42 U.S.C. § 1395x(n); 42 C.F.R. § 414.202.

4. Motions

Given Mrs. Zieroth's passing, Plaintiff has filed a motion to substitute her husband (Mr. Gary Zieroth) as the representative of her estate.

While she was still living, nearly concurrent with the filing of the Complaint, Mrs. Zieroth filed a motion for summary judgment. See Dkt. #11. This Court denied that motion without prejudice. See Dkt. #13. In accordance with the Court's Order, Plaintiff will submit the same motion for summary judgment as soon as the Answer is served.

1 The Secretary intends to file a motion to dismiss at least one claim under Rule 12(b)(6)
2 for failure to meet the pleading standard set forth in the Federal Rules.

3 **5. Amendment of Pleadings**

4 At this time, no amendment of the pleadings is anticipated.

5 **6. Evidence Preservation**

6 Given that this is an administrative review case, it is not believed that this provision is
7 applicable.

8 **7. Disclosures**

9 Given that this is an administrative review case, it is not believed that this provision is
10 applicable.

11 **8. Discovery**

12 Given that this is an administrative review case, it is not believed that this provision is
13 applicable.

14 **9. Class Actions**

15 This is not a class action case.

16 **10. Related Cases**

17 Plaintiff's Statement:

18 As discussed above, there have been multiple prior cases on the identical issue, none of
19 which Mrs. Zieroth was a party to. Of the pending cases on the identical issue, Mrs. Zieroth is
20 not a party to the *Olsen* case and, as a technical matter, is not a party to the *Lewis* class action
21 because no class has been certified yet. Assuming that the class is certified in the *Lewis* matter,
22 Mrs. Zieroth elects to pursue her case individually.

23 In addition, Mrs. Zieroth has multiple pending claims that have been denied by the
24 Secretary and are at various stages of the appeal process.

25 Defendant's Statement:

1 There are two other ongoing suits on the issue of whether a CGM is durable medical
2 equipment within the meaning of the Medicare statute and regulations. *See Olsen v. Azar*, Case
3 No. 19-cv-3814 (D.D.C.); *Lewis v. Azar*, Case No. 18-cv-2929 (D.D.C.). The *Lewis* case is a
4 putative class action.

5 **11. Relief**

6 As set forth in the Complaint, Plaintiff seeks a determination that a CGM is durable
7 medical equipment, a covered Medicare benefit, and an injunction ordering the Secretary to
8 provide coverage for Mrs. Zieroth for the claim at issue in this case.

9 **12. Settlement and ADR**

10 Plaintiff's Statement:

11 Plaintiff does not believe that there are any prospects for settlement. As detailed above,
12 before the Secretary issued the denial at issue in this case, three district courts had already told
13 the Secretary that his position was so lacking in merit that the Secretary was ordered to pay the
14 plaintiff's attorney's fees. Nevertheless, the Secretary continues to issue denials on these same
15 grounds. Because it appears that only repeated public decisions by district courts have any
16 prospect of changing the Secretary's defiance, Plaintiff does not believe that settlement is in
17 either her or the public's interest.
18

19 No ADR efforts have been undertaken to date. The parties submitted their ADR L.R. 3-
20 5(b) certifications on March 20, 2020. See Dkt. #16 and 17. Given its administrative review
21 nature, Plaintiff does not believe that any ADR option is appropriate.

22 Defendant's Statement:

23 The Secretary has been informed that Plaintiff is not interested in any potential
24 settlement.

25 **13. Consent to Magistrate Judge for All Purposes**

26 The parties do not consent to a magistrate judge for all purposes.

27 **14. Other References**

1 This case is not suitable for reference to another process.

2 **15. Narrowing of Issues**

3 Given that this is an administrative review case, Plaintiff does not believe that this
4 provision is applicable.

5 **16. Expedited Trial Procedure**

6 Given that this is an administrative review case, it is not believed that this provision is
7 applicable.

8 **17. Scheduling**

9 Given that this is an administrative review case, Plaintiff does not believe that this
10 provision is applicable because the schedule is dictated by the Local Rule.

11 Plaintiff opposes any effort to further delay the litigation.

12 The Secretary asks the Court to resolve his forthcoming partial motion to dismiss before
13 setting a schedule for summary judgment, to avoid unnecessary summary judgment briefing on
14 claims that do not satisfy the pleading standard set forth in the Federal Rules.

15 **18. Trial**

16 Given that this is an administrative review case, it is not believed that this provision is
17 applicable.

18 **19. Disclosure of Non-party Interests Entities or Persons**

19 Mrs. Zieroth complied with Local Rule 3-15 on January 8, 2020. See Dkt. #2.

20 **20. Professional Conduct**

21 All counsel have reviewed the Guidelines for Professional Conduct for the Northern
22 District of California.

1 Dated: April 3, 2020

Respectfully submitted,

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3 PARRISH LAW OFFICES

4 /s/ James C. Pistorino

5 James C. Pistorino
Attorneys for Plaintiff

6 and

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8 Assistant Attorney General

9 MICHELLE BENNETT
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11 /s/ James Bickford

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